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Ihr Zeichen

Ihr Schreiben

Unser Zeichen Ref. No. WRE/BVI RCALET2.FAX

Köln,

16 Jan.91

Re .: German laws, classification of articles

Dear Richard:

Enclosed please find translated excerpts of the German laws on food products and articles of daily use and the law on pharmaceutical products.

As you may see from these excerpts, the classification is not very consistent:

A pharmacon is defined by its intended use (i. e. for curing illness).

Similarly, cosmetics are defined by their intended use but they may not contain an ingredient which would require a prescription.

Tobacco products primarily have to be made from tobacco. Secondarily their intended use is smoking, chewing, or snuffing.

All remaining products fall into the categories food products and articles of daily use.

As: I understand it, the Minister of Health is entitled to declare any consumer good to be an article of daily use to which more stringent toxicological criteria are applied than to food or tobacco products (see § 5 (3)).

The use of additives in tobacco products is restricted to a positive list, to natural ingredients, and to natural aroma and flavors.

16 Jan.91

Specifically for humectants the overall maximum limit of additives is 5 percent of the "products' dry weight".

I think for any further interpretation we should seek the help of professionals whom Mr. Beecken (PM Munich) could certainly recommend.

Best regards,

Enclosures: Excerpts of laws, translations

Draft agenda for visit 4 to 8 Feb.91

Notes on Ames assay evaluation

SOP for Ames assay

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